

I. REMARKS

This Response is filed with a Request for Continued Examination (RCE), a three month Petition for Extension of Time, and the required fees.

Claims 13-15, 17-21, and 23-36 are pending.

No amendments to the specification or claims are made by this Response.

Rejection under 35 U.S.C. § 102(b) over Lambiase

Claims 13-15, 17-21, and 23-36 were rejected under 35 U.S.C. § 102(b) over Lambiase (WO 98/48002). Applicants traverse the rejection.

Claim 13 of the presently claimed invention is directed to a "method for the treatment of a pathology affecting internal tissues of an eye, comprising identifying a subject in need of treatment of a pathology affecting internal tissues of an eye, topically applying a composition comprising from 10 to 500 µg/ml of nerve growth factor over an ocular surface of a subject in need thereof, wherein said nerve growth factor passes through external tissues of said eye to said internal tissues and wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lens, retina, vitreous body, and choroidea, and treating the pathology affecting the internal tissues of the eye of the subject in need thereof" (emphasis added). Claims 14-15, 17-21 and 23-24 depend from independent claim 13.

Claim 25 of the presently claimed invention is directed to "method for the treatment of a pathology affecting internal tissues of an eye, comprising identifying a subject in need of treatment of a pathology affecting internal tissues of an eye, topically applying a composition comprising from 200 to 500 µg/ml of nerve growth factor over an ocular surface of a subject in need thereof, wherein said nerve growth factor passes through external tissues of said eye to said internal tissues and wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lens, retina, vitreous body, and choroidea, and treating the pathology affecting the internal tissues of the eye of the subject in need thereof" (emphasis added). Claims 26-36 depend from independent claim 25.

In contrast to the presently claimed application, Applicants submit that Lambiase merely discloses the “use of nerve growth factor for the storage of corneas in culture, the *in vitro* production of corneal and conjunctival tissues and the treatment of corneal and conjunctival diseases” (Lambiase, page 1, lines 5-7) (emphasis added). Applicants submit that Lambiase merely discusses treatment of conditions relating to the cornea and conjunctiva, which are not the internal eye tissues of claim 1, which are the “sclera, ciliary bodies, crystalline lens, retina, vitreous body, and choroidea.” Applicants submit that the cornea and conjunctiva are completely different parts of the eye than the internal tissues of claim 1, as noted in the enclosed image depicting the anatomy of the eye (from http://www.eyecareclinic.org/eweb/articles/images/eye_big.gif).

Applicants respectfully disagree with the Examiner’s position that Lambiase anticipates the presently claimed invention “[s]ince the essential elements of the Lambiase composition and method are identical to the instant compositions and methods..., [and] the composition would inherently treat the same disorders as the compositions set forth in the instant application” (Office Action, page 3, 1st paragraph). Applicants acknowledge that in some cases, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. However, Applicants submit that in the present application, the disclosure of the treatment of conditions involving the cornea and conjunctiva does not render the treatment of conditions involving the internal tissues of the eye inherent.

Applicants submit that this position is supported by the case law, and in particular, Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368 (Fed. Cir. 2005). In Perricone, the Court of Appeals for the Federal Circuit (“the Federal Circuit”) addressed the issue of anticipation by inherency and method of use claims. In particular, the Federal Circuit addressed the patentability of claims over a prior art reference, U.S. Patent No. 4,981,845 (the Pereira reference). Among the asserted independent claims of the patents at issue were a claim directed to a “method for treating skin sunburn” and a claim directed to a “method for preventing sunburn damage.” The Pereira reference “teaches a cosmetic composition for topical application and discloses various ingredients in that composition, including skin benefit ingredients,

emollients, emulsifiers, and thickeners.” Id. at 1376. The Pereira reference also identifies the compositions as being “suitable for topical application to the skin or hair.” Id. However, the Pereira reference does not disclose the treatment of skin sunburn.

The Federal Circuit found that the claims directed to the treatment of skin sunburn were not anticipated by the Pereira reference. The Federal Circuit did acknowledge that “[t]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s function, does not render the old composition patentably new to the discoverer.” Id. at 1377 (quoting Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347 (Fed. Cir. 1999)). The Federal Circuit also found that the Pereira reference did anticipate claims directed to the method of preventing sunburn damage. However, the Court found that the method for treating sunburn was not anticipated, because the method of treating sunburn was not inherent in the Pereira reference.

The Federal Circuit rejected arguments that the cited reference inherently functions in the claimed manner when topically applied to the skin. Rather, the Federal Circuit asserted:

“The issue is not, as the dissent and district court imply, whether Pereira’s lotion if applied to skin sunburn would inherently treat that damage, but whether Pereira discloses the application of its composition to skin sunburn. It does not... New uses of old products or processes are indeed patentable subject matter.” Id. at 1378.

The Federal Circuit continued:

“[The claim directed to the treating skin sunburn] recites a new use of the composition disclosed by Pereira, i.e., the treatment of skin sunburn. The district court’s inherent anticipation analysis for this claim contains a flaw. The disclosed use of Pereira’s lotion, i.e., topical application, does not suggest application of Pereira’s lotion to skin sunburn. In other words, the district court’s inherency analysis goes astray because it assumes what Pereira neither disclosed nor rendered inherent. Because Pereira does not disclose topical application *to skin sunburn*, this court reverses the district court’s holding that Pereira anticipates claims 1-4 and 7 of the ‘693 patent.” Id. at 1378-1379.

Applicants submit that the holding in Perricone v. Medicis Pharmaceutical Corp. is relevant to the present application. Like in Perricone, the applied reference (in this case, Lambiase) does not teach the use of the disclosed compound for treatment of the claimed conditions. Lambiase merely discloses the use of nerve growth factor in conditions involving the cornea and conjunctiva. Lambiase does not disclose the use of nerve growth factor in the treatment of conditions involving the “sclera, ciliary bodies, crystalline lens, retina, vitreous body, and choroidea” (claim 1), which are entirely different parts of the eye. Similar to what the Federal Circuit stated in Perricone, the issue is not whether nerve growth factor, *if* applied to eyes afflicted with conditions involving the sclera, ciliary bodies, crystalline lens, retina, vitreous body, or choroidea, would inherently treat those conditions. Rather, the issue is whether the prior art reference, Lambiase, **discloses** the use of nerve growth factor to treat the conditions. Applicants respectfully submit that Lambiase does not, and therefore the rejection over Lambiase is improper.

For at least the above reasons, Applicants submit that Lambiase does not teach each and every element of the presently claimed invention, inherently or otherwise. As such, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 13-15, 17-21, and 23-36 under 35 U.S.C. § 102(b) over Lambiase.

Rejection under 35 U.S.C. § 102(b) over Finkenaar et al.

Claims 13-15, 18-19, 21, 24-28, and 30-36 were rejected under 35 U.S.C. § 102(b) over Finkenaar et al. (EP 0312208). Applicants traverse the rejection.

Independent claims 13 and 25 have been discussed above. Claims 14-15, 18-19, 21, and 24 depend from claim 13. Claims 26-28 and 30-36 depend from claim 25.

Applicants submit that Finkenaar et al. merely discloses “aqueous gel formulations or viscous solutions for the controlled delivery of growth factors to wound site” (Finkenaar et al., page 2, lines 36-37). In particular, Finkenaar et al. discloses “gels for topical or incisional wound healing, gels for healing wounds in the anterior chamber of the eye and low viscosity, aqueous formulations for those applications requiring a

more fluid formulation having a higher water content” (Finkenaur et al., page 2, lines 38-40). Finkenaur et al. discloses, “Wounds that may be healed using the compositions of the present invention are those which result from any accidental or medical injury which causes epithelial damage such as ophthalmic wounds which result from corneal ulcers, radiokeratotomy, corneal transplants, epikeratophakia and other surgically induced wounds in the eye; and cutaneous wounds such as burn wounds, incisional wounds, donor sit wounds from skin transplants, and ulcers...” (Finkenaur et al., page 6, lines 4-7). Applicants note that radiokeratotomy and epikeratophakia, like corneal ulcers and corneal transplants, refer to procedures or conditions involving the cornea (see enclosed excerpt from Stedman’s Concise Medical Dictionary, 3rd edition (1997) defining “keratotomy” and “keratophakia”).

As noted above, Applicants submit that the presently claimed invention is directed to a “method for the treatment of a pathology affecting internal tissues of an eye... wherein said internal tissues of the eye are selected from the group consisting of sclera, ciliary bodies, crystalline lense, retina, vitreous body, and choroidea...” The presently claimed invention is not directed to a method of treating conditions involving the cornea or the anterior chamber of the eye.

Applicants respectfully disagree with the Examiner’s assertion that “inherently, the composition advanced by Finkenaur et al., when applied to the eye, treats the same eye-related disorders as the instant application” (Office Action, page 3, last paragraph). Similar to the above rejection over Lambiase, Applicants submit that the assertion that Finkenaur et al. inherently anticipates the presently claimed invention is improper. Like Lambiase, Finkenaur et al. does not teach or disclose the use of nerve growth factor for the treatment of conditions involving the internal tissues of the eye, specifically the “sclera, ciliary bodies, crystalline lense, retina, vitreous body, and choroidea” (claim 1). Applicants submit that the Federal Circuit’s decision in Perricone v. Medicis Pharmaceutical Corp. also applies to the current rejection. Applicants submit that the issue is whether Finkenaur et al. discloses the use of nerve growth factor to treat the claimed conditions, and Applicants submit that Finkenaur et al. does not. Therefore,

Applicants respectfully submit that Finkenaar et al. does not anticipate the presently claimed invention.

For at least the above reasons, Applicants submit that Finkenaar et al. does not teach or suggest all of the elements of the presently claimed invention, inherently or otherwise. As such, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 13-15, 18-19, 21, 24-28, and 30-36 were rejected over Finkenaar et al.

II. CONCLUSION

Applicants respectfully submit that this application is in condition for allowance and such action is earnestly solicited. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to schedule a personal or telephone interview to discuss any remaining issues.

In the event this response is not timely filed, the Applicants hereby petition for an appropriate extension of time. The fee for this extension, along with any other additional fees which may be required with respect to this response, may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. 026073-00020.

Respectfully submitted,



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RJB/YYK:yyk

Enclosures: Web page with image of anatomy of eye
Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368 (Fed. Cir. 2005)
Excerpt from Stedman's Concise Medical Dictionary, 3rd Edition

HPerricone v. Medicis Pharmaceutical Corp.
 C.A.Fed.,2005.

United States Court of Appeals,Federal Circuit.
 Nicholas V. **PERRICONE**, M.D., Plaintiff-
 Appellant,
 v.

MEDICIS PHARMACEUTICAL CORPORATION,
 Defendant-Cross Appellant.
 No. 05-1022, 05-1023.

Dec. 20, 2005.

Background: Owner of two patents for treating skin conditions with fatty acid ester of ascorbic acid sued pharmaceutical company for infringement. The United States District Court for the District of Connecticut, Christopher F. Droney, J., granted summary judgment for company, and owner appealed.

Holdings: The Court of Appeals, Rader, Circuit Judge, held that:

(1) second patent was invalid on ground of obviousness-type double patenting;

(2) some claims were invalid as anticipated, while others were not; and

(3) denial of attorney fees was not abuse of discretion.

Affirmed in part, reversed in part, vacated in part, and remanded.

Bryson, Circuit Judge, concurred in part, dissented in part, and filed opinion.

West Headnotes

11 Federal Courts 170B 766

170B Federal Courts

170BVIII Courts of Appeals

170BVIII(K) Scope, Standards, and Extent

170BVIII(K)1 In General

170Bk763 Extent of Review Dependent on Nature of Decision Appealed from

170Bk766 k. Summary Judgment.

Most Cited Cases

Federal Courts 170B 802

170B Federal Courts

170BVIII Courts of Appeals

170BVIII(K) Scope, Standards, and Extent

170BVIII(K)3 Presumptions

170Bk802 k. Summary Judgment. Most Cited Cases

Federal Courts 170B 813

170B Federal Courts

170BVIII Courts of Appeals

170BVIII(K) Scope, Standards, and Extent

170BVIII(K)4 Discretion of Lower Court

170Bk813 k. Allowance of Remedy and Matters of Procedure in General. Most Cited Cases

Appellate court reviews district court's grant of summary judgment without deference and its denial of summary judgment for abuse of discretion, drawing all reasonable inferences in favor of nonmovant.

12 Patents 291 312(1.2)

291 Patents

291XII Infringement

291XII(C) Suits in Equity

291k312 Evidence

291k312(1) Presumptions and Burden of Proof

291k312(1.2) k. Patentability and Validity. Most Cited Cases

Patent challenger has burden of proving invalidity by clear and convincing evidence.

13 Patents 291 324.5

291 Patents

291XII Infringement

291XII(C) Suits in Equity

291k324 Appeal

291k324.5 k. Scope and Extent of Review in General. Most Cited Cases

District court's finding of patent invalidity on ground

of double patenting is reviewed on appeal without deference.

[4] Patents 291 ↪120

291 Patents

291V Requisites and Validity of Letters Patent

291k120 k. Patents for Same Invention. Most Cited Cases

“Double patenting” doctrine generally prevents patentee from receiving two patents for same invention.

[5] Patents 291 ↪120

291 Patents

291V Requisites and Validity of Letters Patent

291k120 k. Patents for Same Invention. Most Cited Cases

Non-statutory, or “obviousness-type double patenting” is judicially created doctrine adopted to prevent claims in separate applications or patents that do not recite “same” invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend life of patent protection.

[6] Patents 291 ↪120

291 Patents

291V Requisites and Validity of Letters Patent

291k120 k. Patents for Same Invention. Most Cited Cases

Patent for using fatty acid ester of ascorbic acid to treat skin damaged by oxygen-containing free radicals was invalid on obviousness-type double-patenting grounds, in light of owner's prior patent calling for use of same ester to treat sunburn; sunburn was species of genus of skin conditions covered by later patent.

[7] Patents 291 ↪120

291 Patents

291V Requisites and Validity of Letters Patent

291k120 k. Patents for Same Invention. Most Cited Cases

Terminal disclaimer can be filed for issued patent in order to overcome invalidity based on double patenting. 35 U.S.C.A. § 253.

[8] Patents 291 ↪72(1)

291 Patents

291II Patentability

291II(D) Anticipation

291k72 Identity of Invention

291k72(1) k. In General. Most Cited

Cases

Single prior art reference that discloses, either expressly or inherently, each limitation of patent claim invalidates that claim by anticipation. 35 U.S.C.A. § 102(b).

[9] Patents 291 ↪65

291 Patents

291II Patentability

291II(D) Anticipation

291k63 Prior Patents

291k65 k. Sufficiency of Description.

Most Cited Cases

Under principles of inherency, if prior art necessarily functions in accordance with, or includes, patent claim's limitations, it anticipates. 35 U.S.C.A. § 102(b).

[10] Patents 291 ↪65

291 Patents

291II Patentability

291II(D) Anticipation

291k63 Prior Patents

291k65 k. Sufficiency of Description.

Most Cited Cases

Patent-anticipating inherency is not necessarily coterminous with knowledge of those of ordinary skill in art; artisans of ordinary skill may not recognize inherent characteristics or functioning of prior art.

[11] Patents 291 ↪66(1.12)

291 Patents

291II Patentability

291II(D) Anticipation

291k63 Prior Patents

291k66 Operation and Effect

291k66(1.12) k. Compositions,

Compounds, and Medicinal Preparations. Most Cited Cases

Prior skin cream patent could inherently anticipate subsequent claim for cream using one of its ingredients, even if it listed ingredient without special

emphasis in longer list. 35 U.S.C.A. § 102(b).

[12] Patents 291 ☞ 51(1)

291 Patents

291II Patentability

291II(D) Anticipation

291k50 Prior Knowledge or Use

291k51 Nature and Extent in General

291k51(1) k. In General. Most Cited

Cases

Prior art disclosure of broad genus does not necessarily specifically disclose species within that genus, for purposes of patent anticipation. 35 U.S.C.A. § 102(b).

[13] Patents 291 ☞ 66(1.12)

291 Patents

291II Patentability

291II(D) Anticipation

291k63 Prior Patents

291k66 Operation and Effect

291k66(1.12) k. Compositions,

Compounds, and Medicinal Preparations. Most Cited Cases

Patents for treating sun-damaged skin with fatty acid ester of ascorbic acid were invalid as anticipated by prior art patent for use of such esters in cosmetic compositions; although prior art did not disclose exactly same range of ester concentration, it did disclose “effective amount” ranges recited in patents. 35 U.S.C.A. § 102(b).

[14] Patents 291 ☞ 66(1.12)

291 Patents

291II Patentability

291II(D) Anticipation

291k63 Prior Patents

291k66 Operation and Effect

291k66(1.12) k. Compositions,

Compounds, and Medicinal Preparations. Most Cited Cases

Patent claim calling for treatment of sunburned skin with fatty acid ester of ascorbic acid was not invalid as anticipated by prior art patent for use of such ester in cosmetic compositions; prior art neither expressly nor inherently disclosed use of claimed ester to treat sunburn. 35 U.S.C.A. § 102(b).

[15] Patents 291 ☞ 51(1)

291 Patents

291II Patentability

291II(D) Anticipation

291k50 Prior Knowledge or Use

291k51 Nature and Extent in General

291k51(1) k. In General. Most Cited

Cases

When considering whether prior art method invalidates patent on ground of anticipation, court examines natural and inherent results in that method without regard to full recognition of those benefits or characteristics within art field at time of prior art's disclosure. 35 U.S.C.A. § 102(b).

[16] Patents 291 ☞ 66(1.24)

291 Patents

291II Patentability

291II(D) Anticipation

291k63 Prior Patents

291k66 Operation and Effect

291k66(1.24) k. Process, Method,

and Apparatus Claims in General. Most Cited Cases

Patent for apparatus does not necessarily anticipate, and thus prevent subsequent inventor from obtaining patent on new method of using apparatus. 35 U.S.C.A. § 102(b).

[17] Patents 291 ☞ 66(1.12)

291 Patents

291II Patentability

291II(D) Anticipation

291k63 Prior Patents

291k66 Operation and Effect

291k66(1.12) k. Compositions,

Compounds, and Medicinal Preparations. Most Cited Cases

Patent claims calling for treatment of exposed skin surfaces, and age-affected skin areas, with fatty acid ester of ascorbic acid was invalid as anticipated by prior art patent for use of such esters in cosmetic compositions. 35 U.S.C.A. § 102(b).

[18] Patents 291 ☞ 325.11(2.1)

291 Patents

291XII Infringement

291XII(C) Suits in Equity

291k325 Costs

291k325.11 Disbursements in General

291k325.11(2) Attorney Fees
291k325.11(2.1) k. In General.

Most Cited Cases

Award of prevailing-party attorney fees in patent case involves two-part determination: (1) whether prevailing party has proven exceptional case by clear and convincing evidence, and (2) whether award of attorney fees is appropriate. 35 U.S.C.A. § 285.

[19] Patents 291 ☞ 325.11(2.1)

291 Patents

291XII Infringement

291XII(C) Suits in Equity

291k325 Costs

291k325.11 Disbursements in General

291k325.11(2) Attorney Fees

291k325.11(2.1) k. In General.

Most Cited Cases

Award of prevailing-party attorney fees in exceptional patent case lies within district court's discretion; factors to be considered include closeness of case, tactics of counsel, flagrant or good faith character of parties' conduct, and any other factors contributing to imposition of punitive sanctions or to fair allocation of burdens of litigation. 35 U.S.C.A. § 285.

[20] Patents 291 ☞ 325.11(5)

291 Patents

291XII Infringement

291XII(C) Suits in Equity

291k325 Costs

291k325.11 Disbursements in General

291k325.11(2) Attorney Fees

291k325.11(5) k. Proceedings for

Allowance; Evidence. Most Cited Cases

Finding that patent infringement case was not exceptional, for purpose of awarding attorney fees to prevailing defendant, was not clearly erroneous. 35 U.S.C.A. § 285.

[21] Patents 291 ☞ 325.11(4)

291 Patents

291XII Infringement

291XII(C) Suits in Equity

291k325 Costs

291k325.11 Disbursements in General

291k325.11(2) Attorney Fees

291k325.11(4) k. Award to

Defendant. Most Cited Cases

Denial of attorney fees to prevailing patent infringement defendant was not abuse of discretion. 35 U.S.C.A. § 285.

Patents 291 ☞ 328(2)

291 Patents

291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents

291k328 Patents Enumerated

291k328(2) k. Original Utility. Most Cited Cases

4,981,845. Cited as Prior Art.

Patents 291 ☞ 328(2)

291 Patents

291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents

291k328 Patents Enumerated

291k328(2) k. Original Utility. Most Cited Cases

5,409,693. Invalid in Part.

Patents 291 ☞ 328(2)

291 Patents

291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents

291k328 Patents Enumerated

291k328(2) k. Original Utility. Most Cited Cases

5,574,063. Invalid.

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William J. McNichol, Jr., Reed Smith LLP, of Philadelphia, Pennsylvania, argued for defendant-cross appellant. With him on the brief were Tracy Zurzolo Frisch, Maryellen Feehery and Heather A. Ritch. Of counsel was Charles L. Becker.

Before RADER, BRYSON, and LINN, Circuit Judges.

Opinion for the court filed by Circuit Judge RADER. Concurring in part and dissenting in part opinion

filed by Circuit Judge BRYSON.RADER, Circuit Judge.

On summary judgment, the United States District Court for the District of Connecticut, No. 3:99-CV-01820, determined that all of the asserted claims of Dr. Nicholas V. Perricone's U.S. Patent Nos. 5,409,693 (the '693 patent') and 5,574,063 (the '063 patent') are invalid and, as to the '693 patent', not infringed. Perricone v. Medicis Pharm. Corp., 267 F.Supp.2d 229 (D.Conn.2003). Dr. Perricone seeks reversal of those judgments while Medicis Pharmaceutical Corporation cross-appeals the district court's refusal to declare the case exceptional under 35 U.S.C. § 285 and to award Medicis its attorney fees. Because the district court erred in its anticipation analysis with respect to claims 1-4 and 7 of the '693 patent', this court reverses and remands the judgments on those claims of the '693 patent'. This court otherwise affirms the trial court's decisions of anticipation based on inherency for the remaining claims of the '693 patent' and its double-patenting analysis with respect to claims 9, 11-13, 16, 18, and 19 of the '063 patent'. Finally, this court affirms the district court's denial of Medicis' motion under § 285.

I.

Dr. Perricone's patents claim methods of treating or preventing sunburns (the '693 patent') and methods of treating skin damage or disorders (the '063 patent'). The '693 patent' issued in 1995, tracing priority back to a filing in 1989. The '063 patent' issued in 1996, with priority back to the application that resulted in the '693 patent'. The information added in that continuation-in-part application does not affect this case. Thus, both patents disclose essentially the same subject matter: treatment or prevention of various forms of skin damage through the topical application of ascorbic acid (Vitamin C) in a fat soluble form. See '693 patent', col. 2, ll. 26-34; '063 patent', col. 2, ll. 30-36. Specifically, the patents disclose the topical application of ascorbyl fatty acid ester (e.g., ascorbyl palmitate, ascorbyl laurate, ascorbyl myristate, ascorbyl stearate) with a dermatologically acceptable carrier. See '693 patent', col. 2, ll. 26-34; '063 patent', col. 2, ll. 30-36. Because the carrier, as well as the ascorbyl fatty acid ester, is fat soluble, it can "effectively penetrate skin layers and deliver the active ascorbyl fatty acid ester to the lipid-rich layers of *1372 the skin." '693 patent', col. 4, ll. 4-6; '063 patent', col. 4, ll. 10-12. Upon reaching the lipid-rich layers of skin, the ascorbyl fatty acid ester produces a

number of beneficial effects ranging from the acceleration of collagen synthesis to the scavenging of oxygen-containing radicals caused by exposure to damaging ultraviolet radiation. See '693 patent', col. 5, ll. 30-35, col. 6, ll. 35-50; '063 patent', col. 6, ll. 3-15, col. 7, ll. 30-45.

In 1999, Dr. Perricone sued Medicis, alleging that Medicis infringed both the '693 patent' and '063 patent' with its LUSTRA® line of prescription skin depigmenters. Perricone, 267 F.Supp.2d at 232-33. LUSTRA® is a cream that, with hydroquinone as its active ingredient, reduces the production of melanin, i.e., the pigment in skin. LUSTRA® also includes, *inter alia*, ascorbyl palmitate. Before the district court, Dr. Perricone filed motions for summary judgment of validity and infringement, and Medicis filed a motion for partial summary judgment of invalidity of claims 9, 11-13, 16, 18, and 19 of the '063 patent' on the basis of double patenting, and of claims 1-19 of the '063 patent' and claims 1-4, 7-9, and 13 of the '693 patent' on the basis of anticipation. *Id.* at 233. Medicis also filed motions for partial summary judgment of non-infringement, premised on the invalidity of Dr. Perricone's asserted claims, and for attorney fees under 35 U.S.C. § 285. Aside from the rejected attorney fees request, the district court granted Medicis' motions and denied Dr. Perricone's. *Id.* at 249.

The district court's opinion and the parties' briefs before this court do not disclose the disposition of each claim of the '693 patent' and '063 patent'. The district court's opinion appears to invalidate all of the asserted claims of both patents, yet grants summary judgment of non-infringement only for the '693 patent'. See *id.* Dr. Perricone's opening brief suggests that the district court's non-infringement ruling applies to the asserted claims of both patents. Dr. Perricone's opening brief at 1. Nevertheless, this court need not determine the correct status of each claim. Rather, this court confines its rulings to reversal of a clearly identifiable subset of the '693 patent' claims and trusts the parties to resolve any uncertainty on remand.

II.

[1][2][3] This court reviews a district court's grant of summary judgment without deference and a denial of summary judgment for an abuse of discretion, Electromotive Div. of Gen. Motors Corp. v. Transp. Sys. Div. of Gen. Elec. Co., 417 F.3d 1203, 1209

(Fed.Cir.2005), drawing all reasonable inferences in favor of the nonmovant. This court gives due weight to a patent's presumed validity under 35 U.S.C. § 282 (2000), requiring an accused infringer to prove invalidity by clear and convincing evidence. *Geneva Pharm., Inc. v. Glaxosmithkline PLC*, 349 F.3d 1373, 1377 (Fed.Cir.2003). This court reviews double patenting without deference. *Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1326 (Fed.Cir.1999).

Double Patenting

[4][5] The double patenting doctrine generally prevents a patentee from receiving two patents for the same invention. Thus, this doctrine polices the proper application of the patent term for each invention. The proscription against double patenting takes two forms: statutory and non-statutory. Statutory, or “same invention,” double patenting is based on the language in § 101 of the Patent Act mandating*1373 “a patent” for any new and useful invention. 35 U.S.C. § 101 (2000); *In re Goodman*, 11 F.3d 1046, 1052 (Fed.Cir.1993) (“If the claimed inventions are identical in scope, the proper rejection is under 35 U.S.C. § 101 because an inventor is entitled to a single patent for an invention.”) (citations omitted). Non-statutory, or “obviousness-type,” double patenting is a judicially created doctrine adopted to prevent claims in separate applications or patents that do not recite the “same” invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection. *Gerber Garment Tech., Inc. v. Lectra Sys., Inc.*, 916 F.2d 683, 686 (Fed.Cir.1990) (citing *In re Thorington*, 57 C.C.P.A. 759, 418 F.2d 528, 534 (1969)). This case involves double patenting in this latter category.

Claim 1 of the '693 patent recites:

1. A method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid effective to solubilize in the lipid-rich layers of the skin an amount effective to scavenge therefrom free radicals present as a result of transfer of energy to the skin from the ultraviolet radiation which produced said sunburn.

'693 patent, col. 7. Meanwhile, claim 9 of the '063 patent recites:9. A method for the treatment of skin damaged or aged by oxygen-containing free radicals or oxidative generation of biologically active metabolites which comprises topically applying to

affected skin areas a composition containing an effective amount of an ascorbyl fatty acid ester in a dermatologically acceptable, fat-penetrating carrier such that the ester is percutaneously delivered to lipid-rich layers of the skin.

'063 patent, cols. 8-9. The district court found claim 9 of the '063 patent invalid under the non-statutory double patenting doctrine in view of claim 1 of the '693 patent. In reaching that conclusion, the district court first identified differences between the two claims:(1) claim 9 of the '063 patent teaches a method for treatment of certain skin disorders, while claim 1 of the '693 patent teaches a method for treatment of sunburn; (2) claim 9 of the '063 patent recites the use of “an effective amount of an ascorbyl fatty acid ester ...,” while claim 1 of the '693 patent teaches applying an ascorbyl fatty acid ester “effective to solubilize in the lipid-rich layers of the skin an amount effective to scavenge free radicals present as a result of the transfer of energy to the skin from the ultraviolet radiation which produced [the] sunburn”; and (3) claim 9 of the '063 patent recites the use of “a dermatologically acceptable, fat-penetrating carrier such that the ester is percutaneously delivered to lipid-rich layers of the skin,” while the '693 patent does not explicitly recite the use of a carrier.

Perricone, 267 F.Supp.2d at 240. The district court analyzed those distinctions. In the first place, the district court noted that “sunburn is a species of the genus of skin disorders” covered by the '063 patent. *Id.* Next, consulting the specifications of both patents, the district court concluded that the claimed effective amount in the '063 patent falls within the ranges of effective amounts in the '693 patent. Finally, the district court construed the “effective to solubilize” language in claim 1 of the '693 patent to mean the same thing as the language in claim 9 of the '063 patent requiring “a dermatologically acceptable, *1374 fat-penetrating carrier such that the ester is percutaneously delivered to lipid-rich layers of the skin.” Accordingly, the district court found claim 9 of the '063 patent invalid for obviousness-type double patenting in view of claim 1 of the '693 patent.

Claims 11-13 of the '063 patent all depend from independent claim 9. Thus, the district court's analysis of claim 9 applies equally to claims 11-13. Claim 11 includes an additional limitation specifying a particular range of concentration of the ester. Because that range substantially overlaps the range in claim 5 of the '693 patent (dependent on claim 1 of

the '693 patent), the district court determined that claim 11 of the '063 patent is also obvious in view of claim 5 of the '693 patent. *Id.* at 242. For claims 12 and 13 of the '063 patent, the district court determined that those claims added the same limitations to independent claim 9 as claims 3 and 4 added to claim 1 of the '693 patent. Thus, the district court determined that dependent claims 11-13 fall with claim 9 of the '063 patent for the above reasons. *Id.* at 241.

Independent claim 16 of the '063 patent includes limitations analogous to those in independent claim 9. Accordingly, the district court applied the same reasoning for its double patenting determination of claim 16. *Id.* at 241-42. The district court paid special attention to the additional recitation in claim 16 of specific "tocotrienols," but determined that those tocotrienols are not patentably distinct from the Vitamin E of claim 7 of the '693 patent. Finally, the district court determined that claims 18 and 19 of the '063 patent, which both depend from claim 16 of that patent, are not patentably distinct from claims 4 and 7.

[6] This court first examines the contention that the claims of the '063 patent contain "material differences" from those in the '693 patent. This "material differences" argument does not show that the district court erred in its double patenting analysis. Rather, the district court's analysis specifically addresses differences between the claims of the '693 and '063 patents. For instance, the district court discussed the difference between the recitation in the '063 patent's claim 9 of "a dermatologically acceptable fat-penetrating carrier" and claim 1's recitation of no carrier at all. Thus, the district court cogently reasoned that, based on the specification, the "effective to solubilize" language in claim 1 of the '693 patent means the same thing as the "carrier" language in claim 9. Thus, the difference disappears.

Likewise, the district court properly resolved the apparent difference between treatment of various types of skin damage in claims 9 and 16 of the '063 patent and treatment of sunburn in claim 1. Sunburn is a species of skin damage. As such, this court perceives no error in the district court's determination that the earlier species renders the later genus claims invalid under non-statutory double patenting. See *Eli Lilly & Co. v. Barr Labs., Inc.* 251 F.3d 955, 971 (Fed.Cir.2001) ("[This court's] case law firmly establishes that a later genus claim limitation is

anticipated by, and therefore not patentably distinct from, an earlier species claim.") (citations omitted).

Finally, the district court did not misconstrue the genus-species relationship between claim 16 of the '063 patent and claim 7 of the '693 patent. The district court interpreted the language of claim 16 reciting various tocotrienols, and concluded that it "refers to certain forms of tocopherols, or Vitamin E." *1375 *Perricone*, 267 F.Supp.2d at 238. Thus, the district court did not improperly conclude that a species was obvious in light of an earlier claim to a genus but correctly concluded that there was no patentable distinction between the language of claim 16 of the '063 patent and claim 7 of the '693 patent. This court finds no error in that analysis.

The district court also considered and correctly rejected the suggestion that procedures of the United States Patent and Trademark Office (PTO) militate against double patenting. Specifically, if Dr. Perricone had presented all the claims of the '693 and '063 patents to the PTO in a single application, the PTO might have made a restriction requirement. In other words, the PTO might have separated the claimed subject matter into different classifications and different inventions. If the PTO had entered a restriction requirement under that hypothetical situation, 35 U.S.C. § 121 would have barred a double patenting rejection. Yes, and if the court had a brother, he might like buttermilk. In other words, this tortured hypothetical does not correspond to the record in this case. The various claims were not filed together nor restricted by the PTO. Thus, in simple terms, 35 U.S.C. § 121 does not rescue Dr. Perricone's voluntarily filed continuation-in-part application.

[7] Finally, and contrary to the suggestion by the district court, the Patent Act and PTO rules support the filing of a terminal disclaimer even after issuance of the second patent. See 35 U.S.C. § 253 (2000) ("[A]ny patentee ... may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted"); 37 CFR § 1.321(a) (incorporating the language of § 253). The district court's focus on *In re Goodman*, 11 F.3d 1046, 1052 (Fed.Cir.1993) (explaining that a terminal disclaimer can overcome a double patenting "rejection") seems to have led to its conclusion that a terminal disclaimer cannot be filed for an issued patent to overcome invalidity based on double patenting. The commentary from *In re Goodman* arose in the

context of ex parte prosecution, a setting not applicable to this case. An applicant must always overcome every rejection to gain issuance of a patent. Accordingly, the pre-issuance timing requirement of a terminal disclaimer to overcome a double patenting rejection does not dictate a prohibition on post-issuance terminal disclaimers. A terminal disclaimer can indeed supplant a finding of invalidity for double patenting. See Applied Materials, Inc. v. Semiconductor Materials Am., Inc., 98 F.3d 1563, 1577 (Fed.Cir.1996) (“For obviousness-type double patenting, [the improper extension of the statutory term] problem can sometimes be avoided for co-owned patents ... through the use of a terminal disclaimer.”). This record, however, does not include any evidence of a disclaimer even though the district court invalidated the claims over two years ago. Thus, while Dr. Perricone might still file a terminal disclaimer to overcome prospectively the double patenting basis for invalidity, this court makes no determination about the retrospective effect of such a terminal disclaimer.

Anticipation

[8][9][10] A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1565 (Fed.Cir.1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. See *1376 In re Cruciferous Sprout Litig., 301 F.3d 1343, 1349 (Fed.Cir.2002). “Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates.” *Id.* (quoting MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed.Cir.1999)). Moreover, “[i]nherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art.” *Id.*; see also Schering Corp. v. Geneva Pharms., 339 F.3d 1373, 1377 (Fed.Cir.2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing In re Cruciferous Sprout Litig., 301 F.3d at 1351; MEHL/Biophile, 192 F.3d at 1366).

The district court determined that U.S. Patent No. 4,981,845 (Pereira) anticipates claims 1-4, 7-9, and 13 of the '693 patent, and claims 1-19 of the '063

patent. Perricone, 267 F.Supp.2d at 243. Pereira teaches a cosmetic composition for topical application and discloses various ingredients in that composition, including skin benefit ingredients, emollients, emulsifiers, and thickeners. See Pereira, cols. 1-2. In addition to listing examples, Pereira discloses eight distinct example compositions with specific concentrations of ingredients. *Id.* at cols. 8-12. Pereira identifies the disclosed compositions only briefly, identifying them as “suitable for topical application to the skin or hair.” Pereira, col. 1, ll. 6-8. The district court concluded that Pereira's disclosed use anticipates Dr. Perricone's claims because Pereira's disclosed compositions include all the various ingredients in the concentrations claimed by Dr. Perricone. Thus, according to the district court, the topical application of Pereira's compositions would necessarily yield Dr. Perricone's claimed skin benefits. On appeal, Dr. Perricone argues that: (1) Pereira's disclosed skin benefit ingredients include ascorbyl palmitate among many others, and so Pereira's disclosure does not anticipate the specific claimed use of ascorbyl palmitate; (2) Pereira's disclosed range of concentration of its skin benefit ingredient only partially overlaps with Dr. Perricone's claimed range; and (3) Pereira does not disclose any benefit directed to skin sunburn, or any of the other specific skin disorders, as claimed by Dr. Perricone.

[11] With respect to its skin benefit ingredient, Pereira discloses “from 0.01 to 20% by weight of a skin benefit ingredient chosen from: ... Ascorbyl palmitate [and] Tocopherol [i.e., Vitamin E]” Pereira, col. 1, ll. 55-68. In addition to those two identified ingredients, Pereira lists an additional twelve ingredients. See *id.* In total, Pereira teaches a total of fourteen skin benefit ingredients. This court rejects the notion that one of these ingredients cannot anticipate because it appears without special emphasis in a longer list. To the contrary, the disclosure is prior art to the extent of its enabling disclosure. See Hewlett-Packard Co. v. Mustek Sys., Inc., 340 F.3d 1314, 1324 n. 6 (Fed.Cir.2003) (“The anticipation analysis asks solely whether the prior art reference discloses and enables the claimed invention, and not how the prior art characterizes that disclosure or whether alternatives are also disclosed.”) (citing Celeritas Techs. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361 (Fed.Cir.1998)).

In re Baird, 16 F.3d 380, 383 (Fed.Cir.1994), is not inconsistent with this anticipation analysis. In the first place, In re Baird involved obviousness, not

anticipation. *Baird* observes that “disclosure of *1377 millions of compounds does not render *obvious* a claim to three compounds.” 16 F.3d at 383 (emphasis added). *Baird*’s reasoning, relevant to obviousness, does not apply to Pereira’s disclosure of a handful of different compositions, the use of one of which anticipates Dr. Perricone’s claims.

[12] While other opinions state that disclosure of a broad genus does not necessarily specifically disclose a species within that genus, *see, e.g., Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1262 (Fed.Cir.1989), this axiomatic proposition also does not rescue Dr. Perricone’s claims. In this case, the prior art does not merely disclose a genus of skin benefit ingredients without disclosing the particular claimed ingredient. Rather Pereira specifically discloses ascorbyl palmitate. That specific disclosure, even in a list, makes this case different from cases involving disclosure of a broad genus without reference to the potentially anticipating species. Thus, these cases do not alter the district court’s correct anticipation reasoning.

[13] Pereira’s disclosed range of concentration also does not exactly correspond to Dr. Perricone’s claimed range. Pereira’s disclosure nonetheless discloses and anticipates Dr. Perricone’s particular claimed “effective amount” ranges. Dr. Perricone’s claims recite a number of different ranges associated with the fatty acid ester. Those claimed ranges vary in breadth from an “effective” amount in claim 1 to particular specific ranges in other claims (e.g., “up to 10% by weight,” ‘063 patent, claim 2; “from about 0.025% to about 5% by weight,” ‘063 patent, claim 3; “from about 0.025% to about 10% by weight,” ‘063 patent, claim 22). Pereira discloses a range of concentration “from 0.01 to 20% by weight.” Pereira, col. 1, ll. 55-68. As the district court correctly noted, Pereira’s range entirely encompasses, and does not significantly deviate from, Dr. Perricone’s claimed ranges. Thus, this court sustains the district court’s reading of Pereira’s effective amount disclosure. *See Atlas Powder Co. v. Ireco Inc.*, 190 F.3d at 1342, 1346 (Fed.Cir.1999) (“[W]hen a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim.”) (citing *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 781 (Fed.Cir.1985)).

[14][15] With respect to the particular claimed skin benefits, the district court reasoned that “Pereira will

inherently function in [the claimed beneficial manner] when topically applied to the skin.” *Perricone*, 267 F.Supp.2d at 248. Thus, the district court ultimately based its anticipation analysis on inherency. “In general, a limitation or the entire invention is inherent and in the public domain if it is the ‘natural result flowing from’ the explicit disclosure of the prior art.” *Schering*, 339 F.3d at 1379 (citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 (Fed.Cir.2001); *In re Kratz*, 592 F.2d 1169, 1174 (CCPA 1979)). In some cases, the inherent property corresponds to a claimed new benefit or characteristic of an invention otherwise in the prior art. In those cases, the new realization alone does not render the old invention patentable. *See Atlas Powder*, 190 F.3d at 1347 (“[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s function, does not render the old composition patentably new to the discoverer.”); *1378 *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed.Cir.2001) (explaining that newly discovered results of known processes are not patentable because those results are inherent in the known processes). Thus, when considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure.

Dr. Perricone’s five asserted independent claims recite:

[Claim 1, ‘693 patent] A method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid

[Claim 8, ‘693 patent] A method for preventing sunburn damage to exposed skin surfaces, comprising topically applying to said skin surfaces

[Claim 1, ‘063 patent] A method for the treatment of skin disorders which arise because of depleted or inhibited collagen synthesis which comprises topically applying to affected skin areas

[Claim 9, ‘063 patent] A method for the treatment of skin damaged or aged by ... which comprises topically applying to affected skin areas a composition containing

[Claim 16, ‘063 patent] A method for the treatment of damaged or aging skin and epithelial tissue disorders ... said treatment comprising topically applying to affected tissue areas the combination of

Thus, Dr. Perricone’s independent claims recite

particular skin benefits together with methods of achieving those benefits (i.e., topically applying a particular compound).^{FN*} If Pereira discloses the very same methods, then the particular benefits must naturally flow from those methods even if not recognized as benefits at the time of Pereira's disclosure. Thus, Pereira anticipates if its disclosure of "topical application" satisfies the application step in Dr. Perricone's various asserted claims.

^{FN*} This court notes that while the various claimed beneficial uses appear to be recited in the preambles of Dr. Perricone's claims, the district court construed those claims as being limited by their preambles, *see Perricone*, 267 F.Supp.2d at 237 (determining the scope of various preamble terms), and neither party seems to have challenged that construction. This court agrees that the district court's construction was correct.

[16] Claim 1 of the '693 patent, from which claims 2-4 and 7 ultimately depend, specifically recites application of the fatty acid ester to "skin sunburn." This claim term raises a different problem. The issue is not, as the dissent and district court imply, whether Pereira's lotion *if applied* to skin sunburn would inherently treat that damage, but whether Pereira discloses the application of its composition to skin sunburn. It does not. This court explained in *Catalina Marketing International, Inc. v. Coolsavings.com, Inc.* that a patent to an apparatus does not necessarily prevent a subsequent inventor from obtaining a patent on a new method of using the apparatus. 289 F.3d 801, 809 (Fed.Cir.2002). New uses of old products or processes are indeed patentable subject matter. *See* 35 U.S.C. § 101 (2000) (identifying as patentable "any new and useful improvements" of a process, machine, manufacture, etc.); *In re King*, 801 F.2d 1324, 1326 (Fed.Cir.1986) (principles of inherency do not prohibit a process patent for a new use of an old structure). That principle governs in this case as well.

Claim 1 of the '693 patent recites a new use of the composition disclosed by Pereira,*1379 i.e., the treatment of skin sunburn. The district court's inherent anticipation analysis for this claim contains a flaw. The disclosed use of Pereira's lotion, i.e., topical application, does not suggest application of Pereira's lotion to skin sunburn. In other words, the district court's inherency analysis goes astray because

it assumes what Pereira neither disclosed nor rendered inherent. Because Pereira does not disclose topical application to *skin sunburn*, this court reverses the district court's holding that Pereira anticipates claims 1-4 and 7 of the '693 patent.

Like the district court, the dissent seems to ignore, or at least dismiss as "not substantial[]," the distinction between Dr. Perricone's claimed method and Pereira's disclosed method. Thus, the dissent characterizes both methods the same way: "Pereira describes not only the same product that is claimed in the sunburn patent, but also the same method of using it, i.e., topically applying it to the skin in an amount necessary to have beneficial effects on the skin." Unfortunately, the dissent can make that statement only by dismissing the explicit language of Dr. Perricone's claimed method: "applying to the skin sunburn." '693 patent, claim 1. Skin sunburn is not analogous to skin surfaces generally. Thus, there is an important distinction between topical application to skin for the purpose of avoiding sunburn, and the much narrower topical application to skin sunburn. That distinction highlights the flaw in the dissent's knee brace hypothetical, which suggests that a particular prevention method necessarily anticipates a treatment method. To use a more apt analogy, the disclosure that a sunburn can be prevented by wearing a hat clearly does not anticipate a claim to the discovery that one can treat an existing sunburn by putting on a hat. The dissent attempts to bolster its analogy by comparing the mechanism underlying its knee brace analogy to Dr. Perricone's invention. With that comparison, the dissent drifts even farther from the facts of this case. The alleged anticipating reference here is Pereira, not Dr. Perricone's own teachings. Pereira is silent about any sunburn prevention or treatment benefits, not to mention the mechanisms underlying such uses. If Pereira did teach sunburn prevention, as well as the mechanism behind that prevention, those teachings might suggest that Dr. Perricone's sunburn treatment claims would have been obvious. However, those unrealized possibilities do not alter the analysis in this case where Pereira does not disclose topical application to skin sunburn.

[17] Unlike claim 1, claim 8 of the '693 patent, from which claims 9 and 13 ultimately depend, merely requires application of the composition to exposed skin surfaces. Because all skin surfaces are susceptible to sunburn damage, and because one can only realistically apply a composition to a skin

surface when that surface is exposed, Pereira's "topical application" encompasses the application step of claim 8. Thus, the district court correctly determined that Pereira's disclosure of the topical application of the same composition necessarily anticipates claims 8, 9, and 13 of the '693 patent.

Claim 1 of the '063 patent, from which claims 2-8 of that patent ultimately depend, recites application to "affected skin areas." That claim further recites that those skin areas suffer from "depleted or inhibited collagen synthesis." '063 patent, claim 1. The specification of the '063 patent, meanwhile, explains that such damage results from, *inter alia*, "the natural aging process." '063 patent, col. 1, ll. 46-50. Because*1380 all skin is a victim of that process, claim 1 of the '063 patent ultimately claims merely the topical application of the recited composition. Likewise, claim 9 of the '063 patent, from which claims 10-15 of that patent ultimately depend, recites application of the composition to "affected skin areas" where those areas are further identified as being "aged." As such, because all skin ages, the application step of claim 9 merely requires application of the composition to skin. Similarly, the "affected tissue areas" of claim 16 of the '063 patent, from which claims 17-25 ultimately depend, are identified in that claim as "aging skin." Thus, as with claims 1 and 9 of the '063 patent, claim 16 claims merely the topical application of the recited composition. Because Pereira discloses the very same composition and teaches its topical application, the district court correctly applied the inherency doctrine. Using the same composition claimed by Dr. Perricone in the same manner claimed by Dr. Perricone naturally results in the same claimed skin benefits.

In an effort to support the district court's invalidity ruling on other grounds, Medicis has directed this court's attention to a number of other references that Medicis argues anticipates Dr. Perricone's claims. This court declines to consider grounds for invalidity not relied on by, and not appealed from, the district court.

Infringement

Recognizing that invalidity is an affirmative defense to infringement, the district court granted Medicis' motion for summary judgment of non-infringement of the '693 patent. *Perricone*, 267 F.Supp.2d at 248-49. The district court likewise denied Dr. Perricone's

motion for summary judgment of infringement. Because it reverses the district court's grant of summary judgment on claims 1-4 and 7 of the '693 patent, this court also vacates the district court's summary judgment of non-infringement on those claims.

Attorney Fees

In the cross-appeal, Medicis challenges the district court's denial of its motion for attorney fees under § 285. Medicis asks this court either to remand on the exceptional case question or to "declare the case exceptional without further proceedings." Medicis' opening brief at 64. This court declines that invitation.

[18][19] An award of attorney fees under 35 U.S.C. § 285 involves a two-part determination. First, a district court must determine whether the prevailing party has proven an exceptional case by clear and convincing evidence. *Forest Labs., Inc. v. Abbott Labs.*, 339 F.3d 1324, 1327 (Fed.Cir.2003) (citing *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 669 (Fed.Cir.2000)). This court reviews an exceptional case finding for clear error. *Id.* at 1328. Second, if the district court finds the case exceptional, it must then determine whether an award of attorney fees is appropriate. *Id.* This court reviews that determination for an abuse of discretion. *Id.* (citing *Cybor Corp. v. FAS Techs.*, 138 F.3d 1448, 1460 (Fed.Cir.1998) (en banc)). As this court explained in *Frank's Casing Crew v. Weatherford International*, trial judges enjoy discretion to award attorney fees for good reason, 389 F.3d 1370, 1379 (Fed.Cir.2004). "After presiding over the preparation and trial of the case, the trial judge can best weigh the relevant considerations, such as the closeness of the case, the tactics of counsel, the flagrant or good faith character of the parties' conduct, and any other factors contributing to imposition*1381 of punitive sanctions or to fair allocation of the burdens of litigation." *Id.* (citing *Modine Mfg. Co. v. Allen Group Inc.*, 917 F.2d 538, 543 (Fed.Cir.1990); *S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc.*, 781 F.2d 198, 201 (Fed.Cir.1986)). This case exhibits those considerations.

[20][21] Medicis' arguments appear to focus on the timing and content of various expert reports proffered by Dr. Perricone, the propriety of various responses by Dr. Perricone to Medicis' requests for admissions, and demands made by Dr. Perricone during

settlement negotiations. While the timing and content of some of those documents might be questionable, Medicis points to nothing establishing that the district court committed clear error regarding whether this case is exceptional. Moreover, even if this court determined that this case should have been declared exceptional, the district court's failure to award attorney fees would not rise to an abuse of discretion given that court's familiarity with the various relevant details of Dr. Perricone's conduct in this case.

CONCLUSION

This court affirms the district court's summary judgment of invalidity of claims 1-19 of the '063 patent and claims 8, 9, and 13 of the '693 patent. However, because the district erred in its anticipation analysis of claims 1-4 and 7 of the '693 patent, this court reverses the district court's summary judgment of invalidity as to those claims. Moreover, this court vacates the district court's summary judgment of non-infringement of claims 1-4 and 7 of the '693 patent, but affirms that summary judgment as to the remaining claims in that patent. Finally, this court affirms the district court's denials of Medicis' motion for attorney fees under 35 U.S.C. § 285. This court remands for further proceedings.

COSTS

Each party shall bear its own costs.

*AFFIRMED-IN-PART, REVERSED-IN-PART,
VACATED-IN-PART and REMANDED*
BRYSON, Circuit Judge, concurring in part and dissenting in part.

I concur in most aspects of the court's opinion, including the portions upholding the district court's ruling that claims 1-19 of the "skin disorder" patent, U.S. Patent No. 5,574,063, and claims 8, 9, and 13 of the "sunburn" patent, U.S. Patent No. 5,409,693, are anticipated by U.S. Patent No. 4,981,845 ("the Pereira patent"). I dissent, however, from the portion of the judgment holding that the Pereira patent does not anticipate claims 1-4 and 7 of the sunburn patent. In my view, the differences between the claims that the court invalidates and those that it holds not to be invalid do not justify a difference in outcome. The written description of the sunburn patent is identical to the pertinent portions of the written description of the skin disorder patent in all material respects. The only significant difference between the two patents

for present purposes is that the sunburn patent claims methods for treating and preventing sunburn comprising the topical application of the composition described in the specification, while the skin disorder patent claims a method for treating skin disorders comprising the topical application of the same composition. Moreover, the only difference between the claims of the sunburn patent that this court invalidates and those ***1382** that it upholds is that the former recite methods for preventing sunburn while the latter recite methods for treating sunburn. The differences between the sunburn and the skin disorder patents, and among the claims of the sunburn patent, simply highlight inherent features of the compositions that are disclosed both in the common written description of the two patents in suit and in the Pereira patent. Under our precedents, those differences do not suffice to avoid anticipation.

Claim 1 of the sunburn patent recites:

A method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid effective to solubilize in the lipid-rich layers of the skin an amount effective to scavenge therefrom free radicals present as a result of transfer of energy to the skin from the ultraviolet radiation which produced said sunburn.

Dependent claims 2-4 and 7 recite a method for treating skin sunburn in which the fatty acid ester of ascorbic acid is topically applied to the skin in the form of a composition including a dermatologically acceptable carrier (claim 2), in which the fatty acid ester of ascorbic acid is selected from a group including ascorbyl palmitate (claim 3), in which the fatty acid ester of ascorbic acid is ascorbyl palmitate (claim 4), and in which the composition includes Vitamin E (claim 7). Independent claim 8 and dependent claims 9 and 13 are similar to claims 1, 2, and 7, except that they recite a method for preventing sunburn damage to exposed skin.

In explaining the effectiveness of the claimed method, the sunburn patent states:

The effectiveness of the ascorbyl fatty acid esters in the treatment of ... radiation-induced skin damage ... can be postulated as resulting from the anti-oxidant properties of ascorbic acid per se, which properties are retained to a high degree in the ascorbyl fatty acid ester form, together with the fact that the ascorbyl fatty acid ester form is capable of being delivered in an effective manner.

Sunburn patent, col. 6, ll. 35-43. The patent further explains that “when solubilized in the lipid-rich layers of the skin, the fatty acid ester form of ascorbic acid is capable of scavenging free oxygen-containing radicals, neutralizing other reactive oxidants released extracellularly and intracellularly, and either interfering with or minimizing oxidative generation of metabolites” *Id.* col. 6, ll. 43-47. The patent describes the invention as onewhich involves the topical application of fat-soluble fatty acid esters of ascorbic acid By virtue of the fat-solubility of these fatty acid esters and the further enhancement of this solubility via admixture with fat-penetrating carriers, the active ascorbic acid can be effectively percutaneously delivered to lipid layers so as to bring about these effects and actions

Id. col. 6, ll. 50-63.

The Pereira patent discloses a composition containing each of the components recited in the sunburn patent, and in amounts falling within the same range. In addition, the Pereira patent discloses that the emulsion of the invention comprises “a selected skin benefit ingredient, a special emulsifier and an emollient oil,” which is effective for delivering the skin benefit agent “to subcutaneous regions of the skin.” Pereira patent, col. 1, ll. 14-15; *id.* col. 2, ll. 13-14. Among the skin benefit ingredients listed in the Pereira patent is *1383 ascorbyl palmitate. Pereira further discloses a number of substances for use as the emollient ingredient, including lethicin. *Id.* col. 4, ll. 67-68.

The evidence before the district court established that the Pereira patent discloses topical application of the same substance that is claimed in the sunburn patent, with the same results. Thus, the evidence showed that certain of the skin benefit ingredients of Pereira, including ascorbyl palmitate, operate to benefit the skin by scavenging free radicals. In addition, the evidence showed that lecithin is a dermatologically acceptable carrier that is able to “solubilize the lipid-rich layers of the skin,” as required by the sunburn patent. And the concentration levels of the skin benefit ingredients of Pereira encompass the levels that the sunburn patent asserts are effective in treating and preventing sunburn.

To be sure, Pereira does not expressly refer to the use of the disclosed composition to treat or prevent sunburn. As the district court noted, however, those benefits are inherent in the topical application of the

composition claimed in Pereira. The fact that Pereira does not assert that the emulsion is effective in preventing or treating sunburned skin does not avoid anticipation of the sunburn patent, as long as those benefits are the natural result of the normal use of the Pereira emulsion. See *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1366 (Fed.Cir.1999) (prior art article anticipates because it describes a process that necessarily performs the claimed process; “where ... the result is a necessary consequence of what was deliberately intended, it is of no consequence that the article's authors did not appreciate the results”); *Atlas Powder Co. v. Ireco*, 190 F.3d 1342, 1347 (Fed.Cir.1999) (“Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates.”); *In re King*, 801 F.2d 1324, 1326 (Fed.Cir.1986), quoting *In re Ackenbach*, 18 C.C.P.A. 769, 45 F.2d 437, 439 (1930) (“if a previously patented device, in its normal and usual operation, will perform the function which an appellant claims in a subsequent application for process patent, then such application for process patent will be considered to have been anticipated by the former patented device”). Although Dr. Perricone may have discovered that among the skin benefits of the composition disclosed by Pereira are the prevention and treatment of sunburn, the discovery of a new property of the Pereira composition, when used in accordance with its normal application, is not a sufficient basis for avoiding anticipation. See *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1350-51 (Fed.Cir.2002) (“Brassica has done nothing more than recognize properties inherent in certain prior art sprouts While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new.”); *EMI Group, N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1349 (Fed.Cir.2001) (“The discovery of a previously unappreciated property of a prior art composition ... does not render the old composition patentably new to the discoverer.”); *Atlas Powder*, 190 F.3d at 1349 (“discovery of an inherent property of the prior art [does] not [constitute] the addition of a novel element” and therefore does not serve as patentable subject matter).

This is not a case in which the patentee is claiming a method that consists of a new way of using a previously known product in order to achieve a new result. The Supreme Court long ago explained that “if *1384 an old device or process be put to a new use which is not analogous to the old one, and the

adaptation of such process to the new use is of such a character as to require the exercise of inventive skill to produce it, such new use will not be denied the merit of patentability.” Ansonia Brass & Copper Co. v. Elec. Supply Co., 144 U.S. 11, 18, 12 S.Ct. 601, 36 L.Ed. 327 (1892). Importantly, however, the Court qualified that rule by adding that “the application of an old process or machine to a similar or analogous subject, with no change in the manner of application and no result substantially distinct in its nature, will not sustain a patent even if the new form of result had not before been contemplated.” *Id.*; see also Brown v. Piper, 91 U.S. 37, 41, 23 L.Ed. 200 (1875) (prior art patent for a “corpse preserver” anticipated method for preserving fish and meats that used the same steps; Court held that the new method “was simply the application by the patentee of an old process to a new subject The thing was within the circle of what was well known before, and belonged to the public. No one could lawfully appropriate it to himself, and exclude others from using it in any usual way for any purpose to which it may be desired to apply it.”).

The majority accurately describes that governing principle of law when it states: “If Pereira discloses the very same methods, then the particular benefits must naturally flow from those methods even if not recognized as benefits at the time of Pereira’s disclosure.” That principle, however, leads me to a conclusion different from the one reached by the majority, at least as to the sunburn treatment claims. In my view, the method of using the composition recited in the sunburn patent is not substantially different from the “skin benefit” use described by Pereira. The prevention and treatment of sunburn therefore do not qualify as “new uses” of the composition so as to avoid anticipation. See Catalina Mktg. Int’l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 809-10 (Fed.Cir.2002) (stating, for illustration, that a claimed use of shoe polish to repel water on shoes does not constitute a “new use” of the prior art polish, although a claimed use of the shoe polish to grow hair would so qualify).

Pereira describes not only the same product that is claimed in the sunburn patent, but also the same method of using it, i.e., topically applying it to the skin in an amount necessary to have beneficial effects on the skin. Dr. Perricone’s contribution is simply to recognize that among those skin benefits is the prevention and treatment of sunburn. That identification of a new subset of a previously known property is not entitled to patent protection.

While the majority applies that principle to the sunburn prevention and skin disorder claims, it does not apply the same principle to the sunburn treatment claims, even though those claims recite the same composition and process as are disclosed in Pereira and recited in Dr. Perricone’s other claims. Yet, to use the majority’s language, the treatment of sunburned skin is every bit as much a “particular benefit[] that must naturally flow from [Pereira’s] methods” as the prevention of sunburn and the treatment of skin disorders. Under the majority’s test, the sunburn treatment claims should therefore be anticipated by Pereira just as much as the sunburn prevention claims and the skin disorder treatment claims.

The majority distinguishes the prevention claims of the sunburn patent from the treatment claims of that patent by stating *1385 that because “all skin surfaces are susceptible to sunburn damage, and because one can only realistically apply a composition to a skin surface when that surface is exposed, Pereira’s ‘topical application’ encompasses the application step of claim 8” of the sunburn patent. But precisely the same reasoning applies to the sunburn treatment claims. The majority seems to attach significance to the notion that topical application of Pereira’s emulsion always prevents sunburn, because all skin is subject to sunburn, but that it does not always treat sunburn, because not all skin is sunburned and in need of treatment. That distinction, however, does not stand up: the fact that the sunburn treatment function is pertinent to only a subset of users of the Pereira method (i.e., those already suffering from sunburn) does not mean that Pereira does not anticipate the treatment claims.

Topical application of the Pereira emulsion results in scavenging oxygen-containing free radicals and neutralizing reactive oxidants, whether the skin is sunburned or not. Thus, the effect that underlies both the prevention and treatment of sunburn is present in all cases of topical application of the Pereira composition. For that reason, Pereira anticipates not only the skin disorder and sunburn prevention claims, but also the sunburn treatment claims, which are based on the same underlying chemical processes. To illustrate the point, if it were discovered that using a particular kind of knee brace that was long worn by athletes to provide stability and thus minimize the effect of ligament injuries would also facilitate the treatment of cartilage damage and protect against

further cartilage damage, that subsequent discovery would not give rise to a patentable invention. Moreover, it surely would not be the case that the use of the brace to prevent cartilage damage would be anticipated, but the use of the brace to treat cartilage damage would not, on the ground that all knees are subject to cartilage damage, but only some knees already have it.

The majority illustrates its distinction between sunburn treatment and sunburn prevention with its own analogy, arguing that the prior use of a hat to prevent sunburn would not anticipate the use of a hat to treat sunburn. Yet this analogy is inapt because a hat prevents sunburn by a mechanism, i.e., shade, that does not treat sunburn. In contrast, the mechanism by which a knee brace minimizes the effects of ligament injury, i.e., enhanced stability, is the same mechanism that facilitates treatment of cartilage damage and also prevents further cartilage damage. The same is true here, where the same chemical process treats and prevents sunburned skin.

Furthermore, the majority's distinction between the sunburn prevention claims, which the majority invalidates, and the sunburn treatment claims, which the majority upholds, is inconsistent with its invalidation of all the asserted claims of the skin disorder patent. The majority distinguishes the sunburn treatment claims by focusing on the applicability of the skin damage patent to aging skin, and suggests that "all skin is a victim of [the natural aging process]." The skin damage patent, however, addresses "[a] wide variety of skin diseases and skin conditions in which the skin has undergone some form of accelerated aging." Skin damage patent, col.1, ll. 26-28. Like sunburn, those diseases and conditions are not found in all persons. The majority's distinction appears to rest upon its assertion that "[s]kin sunburn is not analogous to skin surfaces generally." However, there appears to be *1386 no greater specificity in topical application to skin that is sunburned than there is in topical application to skin that is diseased or skin that has suffered from accelerated aging. Accordingly, I submit that the majority's distinction between the treatment claims and the prevention claims is not a satisfactory ground for decision in this case.

This court's decisions in Rapoport v. Dement, 254 F.3d 1053 (Fed.Cir.2001), and MEHL/Biophile International Corp. v. Milgraum, 192 F.3d 1362 (Fed.Cir.1999), are not at odds with the district

court's conclusion in this case. Each of those cases involved a prior art method that was directed at an objective different from the objective of the claimed invention. In *Rapoport*, the prior art was a method for treating anxiety by administering a certain dosage of a particular drug three times a day, while the invention was a method for treating sleep apnea by administering a larger dosage of the same drug at the time of sleep. In *MEHL/Biophile*, the prior art was a method of using a laser to remove tattoos by aligning the laser over the pigmented skin, while the claimed invention was a method of using a laser to remove hair by aligning the laser over hair follicles. Although in each case practicing the prior art method might sometimes have the effect that was the objective of the claimed invention, the court held in each case that practicing the prior art method would not inherently have that effect. Thus, even if the prior art method for tattoo removal were used on skin having hair, it would not anticipate the claimed method in *MEHL/Biophile* because the prior art method did not dictate that the laser be aligned with hair follicles. And even if the prior art treatment of anxiety were used on patients suffering from sleep apnea, it would not anticipate the claimed method in *Rapoport* because the timing of drug administration and the dosages employed in the two treatments were different.

In this case, by contrast, topical application of the Pereira composition to normal skin inherently produces the same chemical processes that underlie the sunburn prevention claims, including scavenging free-oxygen-containing radicals and neutralizing other reactive oxidants. Topical application of the Pereira composition to sunburned skin inherently produces the same processes, which also underlie the sunburn treatment claims. Because the chemical processes that have the effect of treating and preventing sunburn are inherent consequences of the normal use of the Pereira composition, Pereira anticipates all the claims of the sunburn patent, just as it anticipates all the claims of the skin disorder patent.

In substance, the sunburn patent simply selects particular ingredients from among the small class of ingredients identified in Pereira and identifies specific benefits falling within the broader characterization of benefits identified in Pereira. To hold that the treatment claims of the sunburn patent are not anticipated by Pereira is to permit an inventor to secure patent rights to an existing invention merely

upon identifying an inherent benefit of the prior art that had not previously been specifically identified, but that falls within a broader class of benefits already identified in the prior art. Because that result is contrary to the law of inherent anticipation as I understand it, I respectfully dissent from the portion of the court's judgment relating to the treatment claims of the sunburn patent.

C.A.Fed.,2005.
Perricone v. Medicis Pharmaceutical Corp.
432 F.3d 1368, 77 U.S.P.Q.2d 1321

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ker·a·tose (ker'ā-tōs). Keratotic, relating to or marked by keratosis.

ker·a·to·sis, pl. **ker·a·to·ses** (ker'ā-tō'sis, -sēz). Any lesion on the epidermis marked by the presence of circumscribed overgrowths of the horny layer. [kerato- + G. *-osis*, condition]

actinic k., a premalignant warty lesion occurring on the sun-exposed skin of the face or hands in aged light-skinned persons; hyperkeratosis may form a cutaneous horn, and squamous cell carcinoma of low-grade malignancy may develop in a small proportion of untreated patients.

k. follicula'ris [MIM*124200], a familial eruption, beginning usually in childhood, in which keratotic papules originating from both follicles and interfollicular epidermis of the trunk, face, scalp, and axillae become crusted and verrucous; often intensely pruritic.

lichenoid k., a solitary benign papule or plaque, with microscopic features resembling lichen planus, occurring on sun-exposed or unexposed skin.

seborrheic k., **k. seborrhe'ica**, superficial, benign, verrucous, often pigmented, greasy lesions consisting of proliferating epidermal cells, resembling basal cells, enclosing horn cysts; they usually occur after the third decade.

ker·a·to·sul·fate (ker'ā-tō-sūl-fāt). SYN keratan sulfate.

ker·a·to·tome (ker'ā-tō-tōm). SYN keratome.

ker·a·tot·o·my (ker'ā-tot'ō-mē). 1. Any incision through the cornea. 2. An operation making a partial thickness incision into the cornea to flatten it and reduce its refractive power in that meridian. [kerato- + G. *tomē*, incision]

radial k., a k. with radial incisions around a clear central zone. A form of refractive keratoplasty used in the treatment of myopia.

refractive k., modification of corneal curvature by means of corneal incisions to minimize hyperopia, myopia, or astigmatism. In this type of radial keratotomy surgery, performed by excimer laser, pie-shaped pieces of cornea are removed under local anesthetic. The resulting scar tissue formation reshapes the cornea.

ke·ri·on (kē'rē-on). A granulomatous secondarily infected lesion complicating fungal infection of the hair; typically, a raised boggy lesion. [G. *kērion*, honeycomb; a skin disease, fr. *kēros*, beeswax]

ker·nic·ter·us (ker-nik'ter-ūs). Yellow staining and degenerative lesions in basal ganglia associated with high levels of unconjugated bilirubin in infants; may occur with hemolytic disorder such as Rh or ABO erythroblastosis or G6PD deficiency as well as with neonatal sepsis or Crigler-Najjar syndrome; characterized by opisthotonus, high-pitched cry, lethargy, and poor sucking, as well as abnormal or absent Moro reflex, and loss of upward gaze; later consequences include deafness, cerebral palsy, other sensorineural deficits, and mental retardation. SYN bilirubin encephalopathy, nuclear jaundice. [Ger. *Kern*, kernel (nucleus), + *Icterus*, jaundice]

ke·tal (kē'tāl). a hydrated ketone in which hydroxyl groups are esterified with a

△ke·to-. Combining form denoting a ketone group; replaced systematic nomenclature. [Ger.]

ke·to ac·id (kē'tō). An acid containing a ketone group (-CO-) in addition to the acid group.

ke·to·ac·i·do·sis (kē'tō-as-i-dō'sis). In diabetes or starvation, caused by production of ketone bodies.

ke·to·ac·i·du·ria (kē'tō-as-i-dū'rē-ā). of urine having an elevated content of acids.

ke·to·gen·e·sis (kē-tō-jen'ē-sis).¹ M production of ketones or ketone bodies.

ke·to·gen·ic (kē-tō-jen'ik). Giving rise to ketone bodies in metabolism.

ke·to·hep·tose (kē-tō-hep'tōs). A sugar possessing a ketone group.

ke·to·hex·ose (kē-tō-heks'ōs). A sugar possessing a ketone group. SYN hexulose.

ke·tol (kē'tol). A ketone that has a hydroxyl group near the CO group.

ke·tole (kē'tōl). SYN indole (1).

ke·tole group. Carbons 1 and 2 of a ketone (HOCH₂CO-).

ke·to·lyt·ic (kē-tō-lit'ik). Causing the breakdown of ketone or acetone substances, related to oxidation products of glucose and ketone bodies.

ke·tone (kē'tōn). A substance with a carbonyl group linking two carbon atoms; the term is used in medicine and the simplest is acetone.

ke·to·ne·mia (kē-tō-nē'mē-ā). The presence of recognizable concentrations of ketone bodies in the plasma. [ketone + G. *haima*, blood]

ke·ton·u·ria (kē-tō-nū'rē-ā). Enhanced excretion of ketone bodies.

ke·tose (kē'tōs). A carbohydrate with a characteristic carbonyl group.

ke·to·sis (kē-tō'sis). Enhanced production of ketone bodies, as in diabetes mellitus. [ketone + *-osis*, condition]

17-ke·to·ste·roids (kē-tō-stēr'oydz). with a ketone group on C-17, commonly designate urinary metabolites of adrenal and adrenocortical hormones that possess a ketone group at C-17.

ke·to·tic (kē'tot-ik). Pertaining to the presence of ketone bodies, due to excessive production such as occurs in uncontrolled diabetes.

kg kilogram.

kid·ney (kid'nē). One of the two organs (about 11 cm long, 5 cm wide, 2.5 cm thick) lying on either side of the vertebral column, posterior to the peritoneum, the twelfth thoracic and first three lumbar vertebrae. SYN ren [NA] [A. *ren*, kidney; G. *nephros*, kidney; L. *ren*, kidney; G. *amyloid*, amyloid k., a k. in which amyloid is associated with the kidney]

geographic k., k. with coalescence of superficial lesions in herpes keratitis.

herpetic k., inflammation of the cornea (or cornea and conjunctiva) due to herpes simplex virus. SYN herpetic keratoconjunctivitis.

interstitial k., an inflammation of the corneal stroma, often with neovascularization.

metaherpetic k., a postinfectious corneal inflammation in herpetic k. leading to epithelial erosion; not due to virus replication.

neuroparalytic k., SYN neurotrophic k.

neurotrophic k., inflammation of the cornea after corneal anesthesia. SYN neuroparalytic k.

phlyctenular k., an inflammation of the corneal conjunctiva with the formation of small nodules of lymphoid tissue (phlyctenulae) near the corneoscleral limbus.

sclerosing k., inflammation of the cornea complicating scleritis; characterized by opacification of the corneal stroma.

trachomatous k., SEE pannus, corneal pannus.

kerato-, kerat-. 1. The cornea. 2. Horny tissue or cells. SEE ALSO cerat-, cerato-. [G. *keras*, horn]

ker-a-to-ac-an-tho-ma (ker'ă-tô-ak'an-thô-mă). A rapidly growing, umbilicated tumor, usually occurring on exposed areas of the skin, which invades the dermis but remains localized and usually resolves spontaneously. [kerato- + G. *ak-antha*, thorn, + *-oma*, tumor]

ker-a-to-cele (ker'ă-tô-sēl). Hernia of Descemet's membrane through a defect in the outer layers of the cornea. [kerato- + G. *kēlē*, hernia]

ker-a-to-con-junc-ti-vi-tis (ker'ă-tô-kon-jun-cti-vi'tis). Inflammation of the conjunctiva and the cornea.

atopic k., a chronic papillary inflammation of the conjunctiva showing Trantas dots in a patient with a history of hypersensitivity.

epidemic k., follicular conjunctivitis followed by subepithelial corneal infiltrates; often caused by adenovirus type 8, less commonly by other types. SYN virus k.

herpetic k., SYN herpetic keratitis.

infectious bovine k., a disease of cattle caused by the bacterium *Moraxella bovis* and characterized by blepharospasm, conjunctivitis, lacrimation, and corneal opacity and ulceration, usually in the form of a pinkeye (2).

superior limbic k., inflammatory edema of the superior corneoscleral limbus.

ultraviolet k., acute k. resulting from exposure to intense ultraviolet irradiation.

virus k., SYN epidemic k.

ker-a-to-co-nus (ker'ă-tô-kô-nūs). A conical protrusion of the cornea caused by thinning of the stroma; usually bilateral. SYN conical cornea. [kerato- + G. *kōnos*, cone]

ker-a-to-cyst (ker'ă-tô-sist). Odontogenic cyst derived from remnants of the dental lamina, appearing as a unilocular or multilocular radiolucency which may produce jaw expansion; associated with the bifid rib basal cell nevus syndrome.

odontogenic k. (ke-ră'tô-sist), a cyst of the jawbone arising with a high recurrence rate, a common

... and a palisaded basal layer. One manifestation of the basal cell nevus syndrome.

ker-a-to-cyte (ker'ă-tô-sīt). The fibroblastic stromal cell of the cornea.

ker-a-to-der-ma (ker'ă-tô-der'mă). 1. Any horny superficial growth. 2. A generalized thickening of the horny layer of the epidermis. [kerato- + G. *derma*, skin]

mutilating k. [MIM*124500], diffuse k. of the extremities, with the development during childhood of constricting fibrous bands around the middle phalanx of the fingers or toes which may lead to spontaneous amputation.

planta're sulca'tum, hyperkeratosis and fissure formation on the soles. SYN cracked heel.

ker-a-to-ec-ta-sia (ker'ă-tô-ek-tă-zē-ă). A bulging forward of the cornea.

ker-a-to-ep-i-the-li-o-plas-ty (ker'ă-tô-ep-i-thē-ē-plas-tē). A surgical procedure for the repair of persistent corneal epithelial defects. Corneal epithelium is removed and small pieces of donor cornea, with epithelium attached, are placed at the corneoscleral limbus. [kerato- + epithelio- + G. *plastōs*, formed]

ker-a-to-g-e-nous (ker'ă-toj'ē-nūs). Causing a growth of cells that produce keratin and result in the formation of horny tissue, such as fingernails, scales, feathers, etc.

ker-a-to-glo-bus (ker'ă-tô-glô'būs). Congenital anomaly consisting of an enlarged anterior segment of the eye. SYN megalocornea. [kerato- + L. *glōbus*, ball]

ker-a-to-hy-a-lin (ker'ă-tô-hī'ă-lin). The substance in the large basophilic granules of the stratum granulosum of the epidermis. [kerato- + hyalin]

ker-a-toid (ker'ă-toyd). 1. SYN horny. 2. Resembling corneal tissue. [kerato- + G. *eidos*, resemblance]

ker-a-to-lep-ty-n-sis (ker'ă-tô-lep-tin'sis). 1. SYN gutter dystrophy of cornea. 2. An operation for removing the surface of the cornea and replacement by bulbar conjunctiva for cosmetic reasons. [kerato- + G. *leptynsis*, a making thin]

ker-a-to-leu-ko-ma (ker'ă-tô-lū-kô'mă). A white corneal opacity. [kerato- + G. *leukos*, white, + *-oma*, growth]

ker-a-to-l-y-sis (ker'ă-tol'i-sis). 1. Separation or loosening of the horny layer of the epidermis. 2. A disease characterized by a shedding of the epidermis recurring at more or less regular intervals. [kerato- + G. *lysis*, loosening]

ker-a-to-ma (ker'ă-tô-mă). 1. SYN callosity. 2. A tumor. [kerato- + G. *-oma*, tumor]

ker-a-to-ma-la-cia (ker'ă-tô-mă-lă-shē-ă). Dryness with ulceration and perforation of the cornea occurring in cachectic children; results from severe vitamin A deficiency. [kerato- + G. *malakia*, softness]

ker-a-to-me (ker'ă-tôm). A knife used for incising

ker-a-tom-e-ter (ker'ă-tom'ē-ter). An instrument for measuring the curvature of the anterior corneal surface. SYN ophthalmometer. [kerato- + G. *metron*, measure]

ker-a-tom-e-try (ker'ă-tom'ē-trē). Measurement of the radii of corneal curvature.

ker-a-to-mi-leu-sis (ker'ă-tô-mī-lū'sis). Surgical alteration of refractive error by changing the shape of a deep layer of the cornea: the anterior lamella is peeled back, frozen, and recurved on its back surface on a lathe; or, some of the corneal stroma can be removed from the bed with a laser or a knife. [coinage, prob. fr. G. *keras* (kerat-), horn, cornea, + *smileusis*, carving]

ker-a-to-p-a-thy (ker'ă-top'ă-thē). Any corneal disease, damage, dysfunction, or abnormality. [kerato- + G. *pathos*, suffering, disease]

band-shaped k., a horizontal, gray, interpalpebral opacity of the cornea in hypercalcemia, chronic iridocyclitis, and Still's disease.

bullous k., edema of the corneal stroma and epithelium; occurs in Fuchs' epithelial dystrophy, advanced glaucoma and iridocyclitis, and sometimes after intraocular lens implantation.

neuroparalytic k., corneal inflammation or ulceration associated with dysfunction of the ophthalmic branch of the trigeminal nerve.

ker-a-to-pha-kia (ker'ă-tô-fak'ē-ă). Implantation of a donor cornea or plastic lens within the corneal stroma to modify refractive error. [kerato- + G. *phakos*, lens]

ker-a-to-plas-ty (ker'ă-tô-plas-tē). Any surgical modification of the cornea; the removal of a portion of the cornea containing an opacity and the insertion in its place of a piece of cornea of the same size and shape removed from elsewhere. SYN corneal graft. [kerato- + G. *plassō*, to form]

optical k., transplantation of transparent corneal tissue to replace a leukoma or scar that impairs vision.

refractive k., any procedure in which the shape of the cornea is modified, with the intent of changing the refractive error of the eye; for example, if the cornea is flattened, the eye becomes less myopic. SEE keratophakia, keratomileusis, radial keratotomy.

tectonic k., grafting to replace lost corneal tissue.

ker-a-to-pros-the-sis (ker'ă-tô-pros-thē'sis). Replacement of the central area of an opacified cornea by plastic. [kerato- + G. *prosthesis*, addition]

ker-a-to-rhex-is, ker-a-tor-rhex-is (ker'ă-tô-rek'sis). Rupture of the cornea, due to trauma or perforating ulcer. [kerato- + G. *rhexis*, a bursting]

ker-a-to-scle-ri-tis (ker'ă-tô-skle-rī'tis). Inflammation of both cornea and sclera.

ker-a-to-scope (ker'ă-tô-skōp). An instrument marked with lines or circles by means of which the corneal reflex can be observed. [kerato- + G. *skopeō*, to examine]

ker-a-to-s-co-py (ker'ă-tos'kô-pē). 1. Examination of the reflections from the anterior surface of the cornea in order to determine the character and amount of corneal astigmatism. 2. A term first

